



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

JP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/327,563 06/08/99 SVENDSEN A 0776/1F216-U

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

HM22/0825

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10
08/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/327,563

Applicant(s)
Svendsen et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Jun 7, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 77-81, 84-88, 90-93, 97, 113-187, and 192-213 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 121-125 and 192 is/are allowed.

☒ Claim(s) 85, 93, 113-120, 126-187, and 193-213 is/are rejected.

☒ Claim(s) 77-81, 84, 86-88, 90-92, and 97 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/600,908.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

The preliminary amendment filed concurrently with the application amending the specification to insert "Brief Description of the Figures", canceling claims 1-69 and adding claims 70-112 has been entered.

The supplemental preliminary amendment filed April 19, 2000 canceling claims 70-76, 82, 83, 89, 94-96, 98-104 and 107-109 and adding claims 113-192 has been entered.

The second supplemental preliminary amendment filed June 7, 2000 canceling claims 105, 106, 110-112 and 188-191 and adding claims 193-213 has been entered.

Claims 77-81, 84-88, 90-93, 97, 113-187 and 192-213 are pending.

Information Disclosure Statement

This application contains no IDS.

Drawings

The drawings filed concurrently with the application have been objected by Draftsman, please refer to the attached PTO-948 form for details.

Specification

Art Unit: 1652

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. 37 CFR 1.821(d) requires the use of assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of incompliance where the sequence containing more than four amino acids is given without a sequence identifier: page 33, line 28.

Claim Objections

Claims 77-81, 84-88, 90-93 and 97 are objected to because of the following informalities: It appears that "and" is missing in claims 77-81, 84-88, 90-93 and 97 on line 3 before "comprises".

In claims 78, 80, 81 and 90, line 4, "alter" is mistyped.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

158

Claims 85, 93, 113, 118, 119, 126-128, 133, 134, 141, 142, 163-165, 171, 172, 179, 186, 193, 200 and 207 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass mutations in positions corresponding to *Bacillus licheniformis* α -amylase (SEQ ID NO:2) residues F 403, G433, M15, N188, M197 and/or K436. The Examiner is unable to locate adequate support in the specification for such mutations. Thus, there is no indication that a variant α -amylase comprising any of these mutations was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 193-213 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1652

Claims 193-213 are directed to a genus of a variant of α -amylase DNA having substitutions in positions corresponding to specific residues in *Bacillus licheniformis* α -amylase (SEQ ID NO:2).

The specification does not contain any disclosure of the function of all variant sequences. The genus of a variant of α -amylase that comprises these above variant molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally and structurally unrelated proteins are encompassed within the scope of these claims, including partial amino acid sequences. It includes mutant α -amylases with unspecified modified properties and proteins having no enzymatic activity. The specification discloses only a single species of the claimed genus that of SEQ ID NO:2 or highly homologous sequence which exhibits α -amylase activity with changed Ca^{2+} binding properties. This is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Art Unit: 1652

Claims 193-213 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an α -amylase having at least one mutation listed in claim 193, does not reasonably provide enablement for any variant of an α -amylase comprising said mutations that does not have functional and structural limitations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 193-213 encompass a variant with an α -amylase activity and an inactive variant thereof. The specification does not teach how to use said inactive variant. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The specification discloses that residues recited in claim 193 are important in Ca^{2+} binding. However, various combinations of these residues can lead to changes of

Art Unit: 1652

various properties of a parent α -amylase. The specification does not teach which combination of mutations will result in changes of properties other than Ca^{2+} binding in a parent α -amylase. The state of the art does not allow the predictability of the properties based on the structure. Therefore, one skilled in the art would require guidance beyond that provided in the specification as to how to make and use a variant with α -amylase activity having unspecified modified properties. One skilled in the art would require guidance as to how to use a variant having no α -amylase activity. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 120, 135 and 165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 120 and 135 recite "K406". No such residue is present in SEQ ID NO:2. Claims 135 and 165 recite a variant that "further comprises" substitutions at G301 and H405 (emphasis added). These mutations are already recited in base claims 128 and 158, respectively.

Art Unit: 1652

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 128-162, 166-170 and 173-187 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al.

Suzuki et al. teach that primary structures of *Bacillus* α -amylases resemble each other (page 18933, paragraph bridging 1st and 2nd columns). For example, they disclose that the amino acid sequences of *B. licheniformis* (SEQ ID NO:2) and *B. amyloliquefaciens* (SEQ ID NO:4) α -amylases are 80% homologous (ibid; page 18936, Figure 4). Thus, SEQ ID NO:4 is a variant of SEQ ID NO:2 with at least 70% homology and with substitutions at the residues encompassed by claims 128-162, 166-170 and 173-187. Therefore, the Suzuki et al. reference anticipates claims 128-162, 166-170 and 173-187.

Art Unit: 1652

Claims 118, 119, 127, 133, 134, 163, 164, 171 and 172 are rejected under 35 U.S.C. 102(e) as being anticipated by Bott et al.

The following rejection is applied because mutants comprising substitutions at V128, H133 AND A209 have not been disclosed in the grandparent case 08/600,908 and are getting the priority date of the parent case 08/683,838 only. This date is July 18, 1996 which is after filing date of May 14, 1996 of the Bott's patent.

Bott et al. (US Patent 5,763,385, claim 6, for example) teach mutants comprising the same substitutions as claims 118, 119, 127, 133, 134, 163, 164, 171 and 172 of the instant specification. Therefore, the Bott et al. patent anticipates claims 118, 119, 127, 133, 134, 163, 164, 171 and 172.

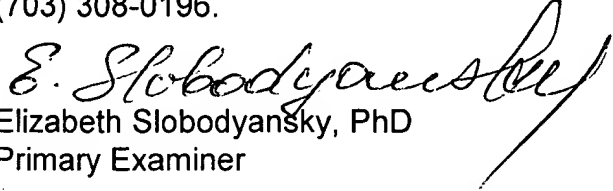
Allowable Subject Matter

Claim 121-125 and 192 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner